Applicant: Burns et al. Attorney's Docket No.: 06275-478US1 / 101028-IP US

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## Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

## Listing of Claims:

- (Currently Amended) Use <u>Method</u> of a coated manufacturing vessel in the manufacture
  of a pharmaceutical formulation <u>for a pMDI</u>, <u>the method</u> comprising:
- <u>charging</u> a drug substance and pharmaceutically acceptable excipients to a <u>conted</u> <u>vessel</u>;
- pressurizing the vessel containing the drug substance and excipients; and
  mixing the drug substance and excipients within the pressurized coated vessel to form a
  suspension for inhalation.
- 2-5. (Cancelled)
- (Currently Amended) Use A method according to claim 1 wherein the drug substance is formoterol furnarate dihydrate.
- (Currently Amended) Use <u>A method</u> according to claim 1 wherein the vessel is a stainless steel vessel.
- 8. (Currently Amended) Use <u>A method</u> according to claim 1 wherein the coating is ECTFE, PVDF or PFA.
- 9. (Currently Amended) Use A method according to claim 1 wherein the coating is PFA.

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(Currently Amended) A device for manufacturing a pharmaceutical composition
comprising a drug substance and pharmaceutically acceptable excipients in the form of a
suspension for inhalation via a pMDI, the device comprising;

-vessel-eharacterised-in that the a vessel having an inner surface that is coated to reduce adhesion of the drug substance to the vessel relative to the extent to which the drug substance would adhere to the vessel if the inner surface were not coated; and

components within the vessel configured to mix the drug substance and excipients to form the suspension, regions of the components that contact the drug substance being coated to reduce adhesion of the drug substance to the components relative to the extent to which the drug substance would adhere to the components if the components were not coated.

- (Currently Amended) A <u>device according to claim 10 wherein the vessel comprises a</u> stainless steel vessel <u>body coated with according to claim 10 wherein the coating is ECTFE</u>, PVDF or PFA.
- (Currently Amended) A <u>device manufacturing vessel</u> according to claim 10 wherein the <u>vessel</u> and components are coated with eoating—is PFA.
- (Currently Amended) A <u>device</u> manufacturing vessel according to claim <u>10</u> [[11]] which further includes coated piping, valves and accessories.
- 14. (New) A device according to claim 10 wherein the vessel comprises a stainless steel body coated with a sintered polymer coating.
- 15. (New) A device according to claim 10 wherein the vessel is configured to be pressurized.
- 16. (New) A method according to claim 1 wherein the drug substance and pharmaceutically acceptable excipients are in the vessel for at least 18.5 hours.
- 17. (New) A method according to claim 1 wherein the mixing step is conducted for about 18.5 hours to two days.

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18. (New) A method according to claim 1 wherein the vessel is coated with a sintered polymer coating.

19. (New) A method according to claim 1 wherein the mixing step is conducted at about  $20^{\circ}\text{C}$ .